

IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

IN RE: TESTOSTERONE REPLACEMENT THERAPY PRODUCTS LIABILITY LITIGATION	MDL No. 2545 Master Docket Case No. 1:14-cv-01748 Hon. Judge Matthew F. Kennelly
This document relates to: MEDICAL MUTUAL OF OHIO, Plaintiff, v. ABBVIE INC., ABBOTT LABORATORIES, ABBOTT PRODUCTS, INC., SOLVAY AMERICA, INC., SOLVAY NORTH AMERICA, LLC, SOLVAY PHARMACEUTICALS, INC., SOLVAY PHARMACEUTICALS SARL, SOLVAY, S.A., AUXILIUM, INC., ELI LILLY AND COMPANY, LILLY USA, INC., ACRUX LIMITED, ACTAVIS PLC, ACTAVIS, INC., ACTAVIS PHARMA, INC., WATSON PHARMACEUTICALS, INC., WATSON LABORATORIES, INC., ANDA, INC., and ENDO PHARMACEUTICALS, INC., Defendants.	No. 1:14-cv-08857

**DEFENDANTS' JOINT MEMORANDUM IN SUPPORT OF THEIR MOTION TO
DISMISS PLAINTIFF MEDICAL MUTUAL OF OHIO'S COMPLAINT**

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Defendants respectfully submit this Joint Memorandum in support of their Motion to Dismiss the Complaint of Plaintiff Medical Mutual of Ohio (“MMO”) pursuant to Federal Rules of Civil Procedure 12(b)(1) and (6).

PRELIMINARY STATEMENT

In this putative class action, MMO sues nearly every company that has sold a testosterone-replacement therapy (“TRT”) drug in the United States in the last 14 years. MMO alleges that, starting in 2000, each such company engaged in “a decade-long deceptive marketing scheme” intended to “transform the male aging process into a curable disease state” called “andropause,” “male menopause,” or “low T.” Each company’s alleged goal was to induce doctors to prescribe its TRT drug “off-label”—*i.e.*, for conditions other than those for which the drugs had received regulatory approval. MMO asserts claims under the federal RICO Act, state statutes, and the common law.

In the last few years, third-party payors (“TPPs”) such as MMO have filed a wave of RICO suits against pharmaceutical companies based on alleged off-label promotion. The ***overwhelming majority*** of these cases have been dismissed as a matter of law¹—including a

¹ See *Ind./Ky./Ohio Reg’l Council of Carpenters Welfare Fund v. Cephalon, Inc.*, 2014 U.S. Dist. LEXIS 69526 (E.D. Pa. May 21, 2014); *Sergeants Benevolent Ass’n Health & Welfare Fund v. Sanofi-Aventis US LLP*, 20 F. Supp. 3d 305 (E.D.N.Y. 2014); *Employer Teamsters-Local Nos. 17/505 Health & Welfare Trust Fund v. Bristol Myers Squibb Co.*, 969 F. Supp. 2d 463 (S.D. W. Va. 2013); *In re Bextra & Celebrex Mktg., Sales Practices & Prods. Liab. Litig.*, 2012 U.S. Dist. LEXIS 111446 (N.D. Cal. Aug. 2, 2012); *Health Care Serv. Corp. v. Pfizer, Inc.*, 2012 U.S. Dist. LEXIS 89759 (E.D. Tex. Apr. 23, 2012), *report and recommendation adopted*, 2012 U.S. Dist. LEXIS 89758 (E.D. Tex. June 28, 2012); *Health Care Serv. Corp. v. Olivares*, 2011 U.S. Dist. LEXIS 117750 (E.D. Tex. Sept. 2, 2011), *report and recommendation adopted*, 2011 U.S. Dist. LEXIS 112544 (E.D. Tex. Sept. 30, 2011); *UFCW Local 1776 v. Eli Lilly & Co.*, 620 F.3d 121 (2d Cir. 2010); *In re Schering-Plough Corp. Intron/Temodar Consumer Class Action*, 2009 U.S. Dist. LEXIS 58900 (D.N.J. July 10, 2009), *aff’d*, 678 F.3d 235 (3d Cir. 2012); *Se. Laborers Health & Welfare Fund v. Bayer Corp.*, 655 F. Supp. 2d 1270 (S.D. Fla. 2009), *aff’d*, 444 F. App’x 401 (11th Cir. 2011); *In re Actimmune Mktg. Litig.*, 614 F. Supp. 2d 1037 (N.D. Cal. 2009), *aff’d*, 464 F. App’x 651 (9th Cir. 2011); *Cent. Reg’l Employees Benefit Fund v. Cephalon*,

virtually identical RICO case in the Southern District of Illinois, *In re Yasmin & Yaz (Drospirenone) Mktg., Sales Practices & Prods. Liab. Litig.*, 2010 U.S. Dist. LEXIS 80758 (S.D. Ill. Aug. 5, 2010) (Herndon, J.). In *Yaz*, as here, the defendant had allegedly marketed its drug “off-label” through advertisements to consumers and events and materials targeting doctors. Judge Herndon found that relevant Circuit authority, as well as a plethora of “[p]ersuasive” out-of-circuit decisions, required dismissal on the pleadings as a matter of law. Most (if not all) of these previous cases involved just *one* pharmaceutical company and *one* drug. Here, by contrast, MMO seeks to maintain a single action against *the entire industry* based on the companies’ alleged fraud in connection with the off-label marketing of their respective TRT drugs.

Just as in *Yaz* and the two dozen other decisions cited above, MMO’s claims suffer from at least three profound and irremediable legal defects.² **First**, the Complaint does not plead facts showing that MMO has standing to sue under RICO or Article III. Specifically, MMO does not satisfy RICO’s proximate causation standard and additionally does not plead facts demonstrating that Defendants’ alleged conduct was a “but-for” cause of an injury cognizable under RICO or Article III. **Second**, the Complaint does not adequately plead a RICO violation because it fails to allege any predicate act of mail or wire fraud by a Defendant (let alone *all* Defendants) with the particularity required by Rule 9(b). And **third**, MMO’s claims are time-barred. MMO’s claims based on state statutes and common law fail for these reasons and others.

Inc., 2010 U.S. Dist. LEXIS 29677 (D.N.J. Mar. 29, 2010); *S. Ill. Laborers’ & Employers Health & Welfare Fund v. Pfizer Inc.*, 2009 U.S. Dist. LEXIS 91414 (S.D.N.Y. Sept. 30, 2009); *Dist. 1199P Health & Welfare Plan v. Janssen*, 2008 U.S. Dist. LEXIS 103526 (D.N.J. Dec. 23, 2008), *subsequent order* at 784 F. Supp. 2d 508, 523-25 (D.N.J. 2011); *In re Epogen & Aranesp Off-Label Mktg. & Sales Practices Litig.*, 590 F. Supp. 2d 1282 (C.D. Cal. 2008), *subsequent order* at 2009 U.S. Dist. LEXIS 58697 (C.D. Cal. June 17, 2009), *aff’d sub. nom. United Food & Comm. Workers Cent. Pa. & Reg’l Health & Welfare Fund v. Amgen, Inc.*, 400 F. App’x 255 (9th Cir. 2010); *Ironworkers Local Union No. 68 v. AstraZeneca Pharms. LP*, 585 F. Supp. 2d 1339 (M.D. Fla. 2008), *aff’d*, 634 F.3d 1352 (11th Cir. 2011).

² Defendants offer additional arguments for dismissal in their individual supplemental briefs.

BACKGROUND

I. The Parties And Their Products

Plaintiff MMO is “[t]he oldest health care insurer in Ohio.” (Compl. ¶ 30.) Defendants are five pharmaceutical companies, or groups of related pharmaceutical companies, that allegedly manufactured and/or distributed TRT drugs: (1) The “Actavis Defendants” (Actavis plc, Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc., Actavis Pharma, Inc., Watson Laboratories, Inc., n/k/a Actavis Laboratories UT, Inc., and Anda, Inc.) allegedly manufactured and/or distributed the TRT drug Androderm, starting on September 29, 1995 (Compl. ¶¶ 44-48, 57, 628); (2) The “AbbVie Defendants” (Solvay S.A., Solvay America, Inc., Solvay North America, LLC, Solvay Pharmaceuticals Sarl, Solvay Pharmaceuticals, Inc., Abbott Products, Inc., AbbVie, and Abbott Laboratories) allegedly manufactured and/or distributed the TRT drug AndroGel starting on February 28, 2000 (Compl. ¶¶ 31-39, 53, 624); (3) Auxilium Pharmaceuticals (“Auxilium”) allegedly manufactured and/or distributed the TRT drugs Testim and Testopel starting in “approximately 2000” and, in any event, by October 31, 2002 (Compl. ¶¶ 40, 54, 625); (4) The “Lilly Defendants” (Eli Lilly and Company, Lilly USA, Inc., and Acrux Limited) allegedly manufactured and/or distributed the TRT drug Axiron, starting in the first quarter of 2011 (Compl. ¶¶ 41-43, 56, 626); and (5) Defendant Endo Pharmaceuticals, Inc. (“Endo”) allegedly manufactured and/or distributed the TRT drug Fortesta, starting on December 29, 2010 (Compl. ¶¶ 49, 58, 627).

The TRT drugs in question all contain synthetic testosterone. The AbbVie Defendants’ AndroGel, Auxilium’s Testim, the Lilly Defendants’ Axiron, and Endo’s Fortesta are administered via topical application (Compl. ¶¶ 53-54, 56); Auxilium’s Testopel is a pellet for subcutaneous implantation (Compl. ¶ 55); and the Actavis Defendants’ Androderm is a transdermal patch (Compl. ¶ 57). Each of these drugs has been approved by “the U.S. Food and

Drug Administration (FDA) for the treatment of abnormally low testosterone in men, a condition known as hypogonadism.” *See In re Testosterone Replacement Therapy Prods. Liab. Litig.* (“TRT”), No. 1:14-cv-01748, Dkt. 526 at 2, 2014 WL 7365872, at*1 (N.D. Ill. Dec. 23, 2014). MMO alleges that none of these drugs has been approved by the FDA for treatment of diminished testosterone levels due to normal aging. (Compl. ¶ 20.) In reality, the FDA’s approval did not impose limitations based on the underlying cause of the patient’s hypogonadism. Regardless, under applicable law, so long as the FDA has approved a drug for any purpose, doctors may prescribe it for either FDA-approved conditions or “off-label” conditions. *See* 21 U.S.C. § 396. (Compl. ¶ 52.) Thus, standing alone, lack of FDA approval of a drug for a particular use does not mean that use for any condition is “medically [in]appropriate.” *Weaver v. Reagen*, 886 F.2d 194, 198 (8th Cir. 1989).

II. Defendants’ Alleged Wrongful Conduct

Although the Complaint acknowledges that the five Defendant groups entered the market at different times between 2000 and 2011, the Complaint alleges that, in 2000 (Compl. ¶¶ 23, 65), the “Defendants” began promoting their respective TRT drugs “off-label” to treat symptoms of normal aging, rather than true “hypogonadism.” Each Defendant group’s alleged plan was to convince doctors that age-related testosterone decline is a treatable “disease state”—known variously as “andropause,” “male menopause,” or “Low T”—rather than a normal and inevitable part of human experience. (Compl. ¶¶ 2, 17.) The goal in doing so was allegedly to induce doctors to write more “off-label” TRT prescriptions, which would in turn be paid for or reimbursed by MMO and other TPPs. (*Id.*) MMO alleges that “andropause” is a myth, and TRT drugs “are ineffective” or “negligibly valuable” for those who do not suffer from hypogonadism. (Compl. ¶¶ 3, 15.) MMO also alleges that TRT drugs have “serious side effects, including heart attacks.” (*Id.*)

MMO alleges that each Defendant group committed multiple acts of mail and wire fraud in furtherance of its alleged off-label promotion. For example, Defendants allegedly “pollut[ed] the medical discourse” by, *inter alia*, covertly sponsoring studies, medical journal articles, seminars, and continuing medical education (CME) courses that exaggerated the prevalence of hypogonadism and the off-label benefits of TRT for “andropause,” and by paying “thought leaders” in the medical community to advocate off-label usage of TRTs for “andropause.” (Compl. ¶¶ 4, 7-9, 66-67, 70-124.) In addition, Defendants allegedly engaged in “consumer directed marketing” of off-label uses via “print, internet, and television advertisements.” (Compl. ¶¶ 12, 68, 125-46.) These ads allegedly touted TRTs to “reverse low libido, a bummed mood, and low energy.” (Compl. ¶¶ 128, 134-35.) Defendants also allegedly encouraged consumers to complete online quizzes that would suggest a diagnosis of “Low T.” (Compl. ¶¶ 138, 141, 153-55, 193, 195, 205, 220, 266, 319, 353-58, 406, 548.)

MMO alleges that each Defendant or Defendant group independently formed several “enterprises” in order to market its respective TRT drug off-label. Each Defendant or Defendant group allegedly formed a “Peer Selling Enterprise” together with various “medical marketing firms” and “physicians” who promoted TRT drugs “to other physicians.” (Compl. ¶¶ 70-107.) Each Defendant or Defendant group allegedly formed a “Publication Enterprise” together with various “medical marketing companies” and “physicians” who performed studies and wrote articles on off-label uses. (Compl. ¶¶ 108-24.) And each Defendant or Defendant group allegedly formed a “DTC [*i.e.*, Direct-to-Consumer] Enterprise” together with various “medical marketing firms” that produced advertisements intended for consumers. (Compl. ¶ 125-46.) Notably, the Complaint ***does not*** allege any conspiracy or collaboration ***across*** the various Defendants or Defendant groups.

Allegedly as a result of these promotional tactics, prescriptions for TRT drugs “skyrocketed,” climbing “170% from 1999 to 2002,” and increasing again “by a factor of five between 2002 and the present.” (Compl. ¶¶ 10-11, 143.) Yet, despite this “astronomical spike in prescriptions,” MMO insists that it was completely “[un]aware” until recently that this increase was “attributable to ineffective, unsafe, and/or non-useful off-label utilization,” rather than use for true hypogonadism. (Compl. ¶¶ 10, 12.) As described further below (*see* Part III.A., *infra*), this is simply not plausible. By 2002 (or earlier), there was widespread public reporting on pharmaceutical companies’ development and marketing of TRT drugs, the prescribing patterns of many physicians with respect to TRT drugs, and the potential benefits and risks of TRT drugs for the off-label conditions specified in the Complaint.

III. MMO’s Alleged Injury And Damages

The Complaint does not discuss MMO’s own reimbursement claims data, even at the most general level. It merely alleges that “Plaintiff and the Class Members have been injured to the extent that they have paid for inappropriate use of TRT drugs and to the extent that Plaintiff and the Class Members have paid or will pay for the health care services and facilities resulting from adverse events associated with TRT drug use,” and that “TPPs” *as a group* “hav[e] been duped by each Defendant into paying billions of dollars for off-label, ineffective, and unsafe TRT drug prescriptions.” (Compl. ¶¶ 28-29, 610-11.) The Complaint does not allege, beyond the conclusory level, that *any identified beneficiary* of MMO actually took any of Defendants’ TRT drugs (let alone *each* of those drugs) without being diagnosed with hypogonadism and/or receiving a clinical benefit. Nor does the Complaint allege, beyond conclusory references to unspecified “adverse events” and “side effects” (Compl. ¶¶ 29, 610), that *any identified beneficiary* of MMO was injured by any TRT drug (let alone by *each* of them) and that MMO paid for resulting health care costs.

LEGAL STANDARD

A complaint “must contain sufficient factual matter, accepted as true, to ‘state a claim to relief that is plausible on its face.’” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). “[C]onclusory statements” and “naked assertion[s]” are properly ignored in this analysis. *Id.* If a complaint’s concrete, well-pleaded facts, taken as true, establish only a “possibility” of liability, or are “merely consistent with” liability, dismissal is required. *Id.* “[I]n a potentially complex litigation, or one that by reason of the potential cost of a judgment to the defendant creates [an] ‘in terrorem’ effect,” a heightened degree of substantiation is necessary. *Limestone Dev. Corp. v. Vill. of Lemont*, 520 F.3d 797, 803 (7th Cir. 2008) (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544 (2007)). This concern is “applicable to a RICO case.” *Id.* In addition, “allegations of fraud in a civil RICO complaint are subject to the heightened pleading standard of Fed. R. Civ. P. 9(b).” *Slaney v. Int’l Amateur Athletic Fed’n*, 244 F.3d 580, 597 (7th Cir. 2001).

ARGUMENT³

I. MMO Lacks Standing Under The RICO Act And Article III

MMO asserts three direct RICO claims and a RICO conspiracy claim against each of the five Defendant groups based on alleged mail and wire fraud in connection with the alleged off-label promotion of their respective TRT drugs. In order to maintain these claims, MMO must plead facts showing that it has standing to sue under Article III of the Constitution, *see Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992), and the RICO Act, *see* 18 U.S.C. § 1964(c).

Article III standing requires allegations that the plaintiff (1) has “suffered an ‘injury in fact,’” that is (2) “fairly traceable to the challenged action of the defendant, and not the result of

³ Pursuant to Case Management Order No. 12, each Defendant reserves the right to challenge personal jurisdiction at the time of remand of this directly filed case.

the independent action of some third party not before the court” and (3) likely to be “redressed by a favorable decision.” *Lujan*, 504 U.S. at 560-61 (internal quotations and citations omitted).

RICO imposes still more stringent standing requirements for private causes of action under 18 U.S.C. § 1964(c). A RICO plaintiff must allege facts showing that it (1) has sustained an injury to its “business or property” (2) “by reason of” a violation of 18 U.S.C. § 1962. 18 U.S.C. § 1964(c); *see also In re Schering Plough Corp. Intron/Temodar Consumer Class Action*, 678 F.3d 235, 246 (3d Cir. 2012); *Evans v. City of Chicago*, 434 F.3d 916, 924 (7th Cir. 2006). In other words, a plaintiff must plead facts showing both proximate causation and “but-for” causation, *Holmes v. Sec. Investor Prot. Corp.*, 503 U.S. 258, 265-66, 268 (1992), and that it has suffered the type of injury RICO was enacted to prevent and redress. *Pirelli Armstrong Tire Corp. Retiree Med. Benefits Trust v. Walgreen Co.*, 631 F.3d 436, 443-45 (7th Cir. 2011).

Numerous courts have dismissed similar RICO claims brought by TPPs for lack of statutory or Article III standing because, under circumstances such as those at bar, TPPs cannot show that the defendant’s alleged racketeering activity resulted in a *direct* injury to them. Indeed, MMO does not even plead facts showing that each Defendant group’s alleged acts of mail and wire fraud were a but-for cause of an injury. And MMO does not plead facts alleging that it has suffered the type of injury to business or property that RICO protects.

A. MMO Cannot Establish Proximate Causation

MMO’s RICO claims should be dismissed because it cannot possibly satisfy RICO’s proximate cause standard, which limits standing to sue to only those plaintiffs injured as a *direct* result of a RICO violation. In this case, the purported connection between each Defendant group’s alleged mail and wire fraud and MMO’s alleged injury involves too many steps and too many independent decisions by unconnected intermediaries to support a civil RICO claim.

In *Holmes*, the Supreme Court held that, to establish proximate cause, a RICO claimant must demonstrate “some **direct** relation between the injury asserted and the injurious conduct alleged.” 503 U.S. at 268 (emphasis added). This requires a direct causal relation; mere foreseeability of injury to the plaintiff is insufficient, even if the injury was specifically intended by the defendant. *Hemi Grp., LLC v. City of New York, N.Y.*, 559 U.S. 1, 12 (2010) (“The concepts of direct relationship and foreseeability are of course two of the ‘many shapes [proximate cause] took at common law.’ Our precedents make clear that in the RICO context, the focus is on ... directness....”) (quoting *Holmes*, 503 U.S. at 268); *see also Anza v. Ideal Steel Supply Corp.*, 547 U.S. 451, 457-58 (2006) (plaintiff alleging foreseeable and intentional but indirect injuries did not show proximate causation under RICO).

A plaintiff cannot establish the requisite direct causal relation where “[m]ultiple steps ... separate the alleged fraud from the asserted injury,” because RICO’s standard for proximate cause “[does] not ... go beyond the first step.” *Holmes*, 503 U.S. at 271-72 (internal quotation marks and citation omitted). And for good reason: as the Supreme Court explained, “the less direct an injury is, the more difficult it becomes to ascertain the amount of a plaintiff’s damages attributable to the [RICO] violation, as distinct from other, independent factors,” and the more difficult it is to “apportion[] damages among plaintiffs removed at different levels of injury from the violative acts.” *Id.* at 269. The directness requirement is necessary so as not to “open the door to ‘massive and complex damages litigation, which would not only burden the courts, but would also undermine the effectiveness of treble-damages suits.’” *Id.* at 274.

In *Hemi*, the City of New York filed RICO claims against an online cigarette wholesaler that failed to comply with a statute requiring submission of customer information so that the city could collect cigarette sales taxes directly from the customers. 559 U.S. at 4. In upholding the

grant of a motion to dismiss, the Supreme Court plurality acknowledged that even if the city's loss of tax revenue was foreseeable to—and, indeed, *specifically intended* by—the wholesaler, the city could not state a RICO claim because the multiple intervening steps between the wholesaler's mail fraud and the city's lost tax revenue precluded a finding of a “direct relationship” between the predicate acts and the alleged injury. *Id.* at 12. The intervening, independent actions of the cigarette purchasers in deciding not to pay the taxes owed led the Supreme Court to conclude that proximate causation could never be established. *Id.* at 15-16.

Closer to the present fact pattern, the Seventh Circuit has held that RICO's proximate causation requirement prevents TPPs from bringing claims against a cigarette manufacturer for deceptive marketing that allegedly increased the TPPs' costs of providing healthcare to their beneficiaries. *Int'l Bhd. of Teamsters, Local 734 Health & Welfare Trust Fund v. Philip Morris Inc.*, 196 F.3d 818, 820-24 (7th Cir. 1999). The TPPs alleged that the medical claims they paid were the result of misrepresentations by the manufacturers about the healthfulness of cigarettes. *Id.* In requiring dismissal of the RICO claims at the 12(b)(6) stage, the Seventh Circuit held that proximate cause was lacking: “[t]he injury for which the plaintiffs seek compensation is remote indeed, the chain of causation long” *Id.* at 825. The court noted that the alleged misrepresentations were not made to the TPP plaintiffs, and, accordingly, the relationship between the predicate acts and the alleged damages “ha[d] too many intermediate steps.” *Id.* at 826; *see also Mendelovitz v. Vosicky*, 40 F.3d 182, 185 (7th Cir. 1994) (finding lack of proximate cause where causal chain “pass[ed] through many intermediaries” and plaintiff's damages “require[d] actions and decisions by third parties before coming into being”).

In keeping with these Supreme Court and Seventh Circuit decisions, many other courts have held that, as a matter of law, the chain of causation between a manufacturer's alleged off-

label promotion and a TPP's payment for any particular prescription is too long and involves too many intermediate actors to satisfy RICO's proximate cause standard. Notably, in *UFCW Local 1776 v. Eli Lilly & Co.*, 620 F.3d 121, 134 (2d Cir. 2010), *cert. denied*, 131 S.Ct. 3062 (2011), the Second Circuit directed summary judgment on RICO claims brought by TPPs because the "attenuated link between the alleged misrepresentations made to doctors and the ultimate injury to the TPPs" made it impossible for the TPPs to establish proximate causation. The TPPs' "theory of liability rest[ed] on the independent actions of third and even fourth parties" that "play[ed] a role in the chain between [the manufacturer] and TPPs." *Id.* (internal quotation marks and citation omitted).

Similarly, in *United Food & Commercial Workers Central Pennsylvania & Regional Health & Welfare Fund v. Amgen, Inc.*, 400 F. App'x 255, 257 (9th Cir. 2010), the Ninth Circuit affirmed dismissal of RICO and state consumer protection claims arising out of a defendant's allegedly fraudulent marketing of two prescription drugs for off-label uses. *Id.* at 257; *see also In re Epogen & Aranesp Off-Label Mktg. & Sales Practices Litig.*, 2009 U.S. Dist. LEXIS 58697, at *6 (C.D. Cal. June 17, 2009) (underlying district court decision), *aff'd*, 400 F. App'x 255 (9th Cir. 2010). The Ninth Circuit held in part that the TPPs "failed to plead a cognizable theory of proximate causation that links [the defendant's] alleged misconduct to [the TPPs'] alleged injury." *Amgen*, 400 F. App'x at 257. In particular, "the complaint proffered an attenuated causal chain that involved at least four independent links" separating [the defendant's] alleged fraud and the TPPs' supposed injuries. *Id.* (noting the links: (1) the U.S. Pharmacopeia-Drug Information's listing of the drug; (2) Medicare's decision to cover the use; (3) the TPPs' decisions to cover the use; and (4) doctors' decisions to prescribe for the use).

Applying the proximate cause analysis of the Supreme Court in *Holmes* and *Anza*, and the Seventh Circuit in *Phillip Morris*, a district court from this Circuit granted a motion to dismiss a TPP's RICO claims against a pharmaceutical company for failure to allege proximate cause under circumstances almost identical to those alleged here. *Yasmin*, 2010 U.S. Dist. LEXIS 80758, at *23. The court dismissed a RICO complaint alleging off-label promotion of a birth control drug, concluding "multiple steps separate the alleged wrongful conduct [off-label promotion] and the alleged injuries (paying 'too much' for 'too many') ... prescriptions, including patient preference, the independent judgment of the prescribing physician, and the reimbursement decision rendered by the third party payor and its benefits manager." *Id.* at *23.

District courts around the country similarly have dismissed RICO claims by TPPs against pharmaceutical companies because the purported connection between a pharmaceutical company's marketing of prescription drugs and a TPP's alleged injuries involves too many steps and too many independent decisions by unconnected intermediaries. *See, e.g., Emp'r Teamsters-Local Nos. 175/505 Health & Welfare Trust Fund v. Bristol Myers Squibb Co.*, 969 F. Supp. 2d 463, 475 (S.D. W. Va. 2013) ("Plaintiffs' [state-law] claims do not satisfy the 'direct relation' test found in *Holmes*" because "[b]etween [d]efendants' alleged misleading marketing and [p]laintiffs' prescription reimbursements lies a vast array of intervening events, including the 'independent medical judgment' of doctors") (citation omitted); *Ironworkers Local Union No. 68 v. AstraZeneca Pharm. LP*, 585 F. Supp. 2d 1339, 1345 (M.D. Fla. 2008) (dismissing RICO and consumer fraud claims brought by TPPs against pharmaceutical companies because "[p]laintiffs' alleged harm is simply too remote from [d]efendants' alleged RICO violation to satisfy the proximate cause requirement"), *aff'd on other grounds*, 634 F.3d 1352 (11th Cir. 2011); *Pa. Employees Benefit Trust Fund v. Astrazeneca Pharm. LP*, 2009 U.S. Dist. LEXIS 76555, at *16

(M.D. Fla. July 18, 2009) (“Plaintiff’s alleged harm is simply too remote from [d]efendant’s alleged unlawful acts to permit a ‘socially and economically desirable’ outcome.”). As one court put it, given “the independent and individualized decision-making of physicians prescribing” a particular drug, there is “a substantial question as to whether [TPPs] could *ever* properly plead proximate causation.” *Dist. 1199P Health & Welfare Plan v. Janssen, L.P.*, Nos. 06-3044 (FLW) et al., 2008 U.S. Dist. LEXIS 103526, at *35 (D.N.J. Dec. 23, 2008) (emphasis added) (finding that the role of prescribing physicians broke “any chain of causation between [d]efendants’ alleged misconduct and [p]laintiffs’ payment for the medication”) (citing *Holmes*, 503 U.S. at 268). After all, the attenuated causal chains posed by such theories would require “precisely the type of ‘intricate, uncertain inquir[y]’ the *Holmes* Court sought to prevent.” *Ironworkers*, 585 F. Supp. 2d at 1344 (citation omitted) (recognizing that an “individualized inquiry would likely have to be conducted as to each consumer purchase transaction or [TPP] reimbursement payment”).

MMO’s Complaint is no different than the legally deficient TPP complaints described above. It simply alleges: (1) each Defendant group used the mails and wires to disseminate misleading information to promote the sale of its TRT drug for treatment of off-label conditions; (2) MMO decided to place that TRT drug on its formulary (without any prior authorization requirement or other safeguard to prevent off-label prescription); (3) unspecified physicians decided to prescribe a particular Defendant group’s TRT drug to an MMO beneficiary to treat an off-label condition; (4) the MMO beneficiary decided to fill the TRT prescription and use the particular TRT drug; (5) MMO decided to cover and pay for that TRT prescription; and (6) MMO paid the relevant Defendant for that TRT prescription. (Compl. ¶¶ 65-146, 610-20.) Any connection between each Defendant group’s alleged off-label promotion and the alleged loss

suffered by MMO thus involves multiple steps and actions by independent licensed professionals, consumers, and MMO. The connection between the challenged conduct and the purported loss is anything but “direct” as Supreme Court and Seventh Circuit case law requires. In keeping with these controlling precedents and the numerous district court decisions cited above, MMO’s RICO claims against each Defendant group should be dismissed with prejudice because MMO cannot satisfy RICO’s proximate cause requirement.

Indeed, the lack of proximate cause is even clearer here than in other TPP RICO cases. Most (if not all) previous cases involved just *one* pharmaceutical company and *one* drug. Here, by contrast, MMO alleges that *the entire industry* marketed their respective TRT drugs for off-label uses, and that *numerous* companies contributed (through independent and uncoordinated acts) to the “andropause” movement, and consequently, to the collective demand for such drugs. Thus, any given doctor’s decision to prescribe a particular TRT drug for any given patient might have been attributable to *any number* of independent industry actors (or, as in other TPP RICO cases, to no industry actor at all). This sort of situation is the very reason why RICO’s directness requirement exists. See *Holmes*, 503 U.S. at 269 (“the less direct an injury is, the more difficult it becomes to ascertain the amount of a plaintiff’s damages attributable to the [RICO] violation, as distinct from other, independent factors”); *Anza*, 547 U.S. at 459-60 (finding lack of proximate cause where “it would require a complex assessment to establish what portion of [plaintiff’s] lost sales were the product of” the named defendant’s challenged conduct).

In the face of this overwhelming authority, MMO may argue that the requirement of a direct causal connection can be ignored because it was a foreseeable victim of each Defendant group’s alleged scheme. MMO may claim that *Bridge v. Phoenix Bond & Indemnity Co.*, 553 U.S. 639 (2008), endorsed this “foreseeability” approach to proximate cause in RICO actions,

and it will point to *In re Neurontin Mktg. & Sales Practices Litig. (Kaiser)*, 712 F.3d 21 (1st Cir. 2013), *cert. denied* 134 S.Ct. 786 (2013), as a model. Yet, as many courts have recognized, the “foreseeability” argument “directly contradicts the relevant Supreme Court precedent,” which requires *directness*. *In re Bextra & Celebrex*, 2012 U.S. Dist. LEXIS 111446, at *225 (N.D. Cal. Aug. 2, 2012) (discussing *Anza*, *Bridge* and *Hemi*); *see also Yasmin*, 2010 WL 3119499, at *7 (rejecting foreseeability as test for proximate cause in TPP’s RICO claim in favor of directness test).

In *Anza*, the Supreme Court reversed a decision by the Second Circuit, which had held that RICO’s proximate-cause requirement could be satisfied, even if the chain of causation was indirect, if the plaintiff was the “intended victim of the [defendant’s] scheme.” 547 U.S. at 460. The Supreme Court criticized that reasoning, stating that “[a] RICO plaintiff cannot circumvent” RICO’s requirement of a direct causal connection merely because the alleged injury was “the defendant’s aim.” *Id.* at 460; *see also James Cape & Sons Co. v. PCC Constr. Co.*, 453 F.3d 396, 403-04 (7th Cir. 2006) (following *Anza*). In a lone partial dissent, Justice Thomas disagreed with the Court’s “stringent” approach to proximate cause, arguing that a RICO claim should be available against “tortfeasors who cause[] injury ... through a two-step process” where the second step is “foreseeable” or “intended.” *Anza*, 547 U.S. at 463, 470. But that approach commanded no other votes.

Two years later, in *Bridge*, 553 U.S. at 641, the Supreme Court reviewed a RICO claim predicated on a scheme to rig auctions of county tax liens on real property. The question was whether the plaintiff had to plead “first-party reliance” on a fraudulent statement to state a RICO claim. The Supreme Court held that allegations of first-party reliance were not necessary in that particular context and that the plaintiff could state a claim based on a third-party’s (the

auctioneer's) reliance on the fraudulent bids. *See Hemi*, 559 U.S. at 14 (discussing *Bridge*). In this context, the Supreme Court remarked that the plaintiff's injury "was a foreseeable and natural consequence of [the defendants'] scheme" to manipulate the auction process. *Id.* at 28. However, this offhand remark was not intended to change *Anza*'s direct relationship requirement. No case law was cited in connection with the remark. And the Supreme Court did not hold, or even suggest, that a plaintiff could satisfy RICO's proximate cause standard simply by alleging that it was a foreseeable victim of a mail or wire fraud scheme. Indeed, *Bridge* purported to *follow* *Anza* (not overrule it), and *Bridge* took as a given that "the central question" in the proximate-cause analysis is "whether the alleged violation led *directly* to the plaintiff's injuries," and that proximate cause is absent where "*other, independent* factors" may have contributed to the plaintiff's injuries. *Bridge*, 553 U.S. at 654 (emphasis added).

Two years after *Bridge*, in *Hemi*, a plurality of the Court noted *Anza*'s disavowal of "foreseeability" and "intent" in the proximate-cause analysis: "Our precedents make clear that ... the focus is on the directness of the relationship between the conduct and the harm. Indeed, *Anza* and *Holmes* never even mention the concept of foreseeability. 559 U.S. at 12. In *Hemi*, neither the plurality nor the dissent viewed *Bridge* as having overruled *Anza* and having endorsed a "foreseeability" or "intent" approach to RICO's proximate causation requirement. Thus, there is a uniform line of Supreme Court authority (1) holding that RICO's proximate causation standard limits standing to those plaintiffs injured as a "direct" result of an alleged RICO violation and (2) rejecting "foreseeability" or "intent" as a test for proximate cause.⁴ *See also*

⁴ The Seventh Circuit's decision in *BCS Services, Inc. v. Heartwood 88, LLC*, 637 F.3d 750 (7th Cir. 2011), also does not help MMO. *BCS* was based on the same facts as *Bridge*—an unusual situation where the intermediate party had no causal influence. The only "step" between the alleged misrepresentation and the alleged injury was a random selection; repeated enough times, the randomness disappeared, and the outcome of the fraudulent scheme was preordained

Lexmark Int’l, Inc. v. Static Control Components, Inc., 134 S.Ct. 1377, 1391 (2014) (citing *Anza* with approval in a case concerning proximate cause under the Lanham Act).

Neurontin, 712 F.3d at 38, is the **only** circuit court decision that endorses a “foreseeability” test for establishing proximate cause under RICO. But *Neurontin*’s “foreseeability” holding is based entirely on a misreading of *Bridge* and on the **dissenting** opinion in *Anza*. *Id.* at 39. *Neurontin* thus conflicts with the Supreme Court’s decisions in *Anza*, *Bridge*, and *Hemi*, the Seventh Circuit’s decisions in *Philip Morris*, *Mendelovitz*, and *James Cape*, and numerous other cases, such as *Yasmin*, 2010 WL 3119499, at *7, which expressly reject foreseeability and intent as a legal test for proximate cause. This Court should follow the overwhelming majority of cases and dismiss MMO’s Complaint with prejudice for inability to satisfy RICO’s proximate causation requirement.

B. MMO Fails To Plead “But-For” Causation

In addition, MMO’s Complaint fails to plead facts that plausibly show that alleged mail and wire fraud by each Defendant was a but-for cause of MMO’s alleged injury. To satisfy RICO’s “but-for” causation requirement, a plaintiff must plead facts establishing that its alleged injury would not have occurred absent the defendant’s racketeering activity. *Holmes*, 503 U.S. at 268; *Hemi*, 559 U.S. at 9; *Bridge*, 553 U.S. at 649 (in a RICO action predicated on mail or wire fraud, plaintiff must allege that “**someone’s** reliance on a misrepresentation” was the but-for cause of the plaintiff’s alleged injury) (emphasis by the Court).

as a matter of mathematical law. Thus, unlike here, the causal relationship in *BCS* was direct. As to ordinary scenarios where intermediaries’ intentional conduct impacted the causal chain, *BCS* acknowledged that proximate cause would be lacking. 637 F.3d at 756 (“[t]here is ... reason for worrying about imposing liability” when violation and injury “are separated by intermediate pairs of cause and effect”).

Consistent with *Holmes*, *Bridge*, and *Hemi*, courts have dismissed numerous RICO claims brought by TPPs against pharmaceutical companies because the TPPs failed to plead concrete, non-conclusory facts showing that they had paid for prescription drugs as the result of the challenged conduct of the defendant and not the independent action of a doctor, patient, or other party not before the court. See *In re Actimmune Mktg. Litig.*, 614 F. Supp. 2d 1037, 1052 (N.D. Cal. 2009), *aff'd*, 464 F. App'x 651 (9th Cir. 2011); *Bextra & Celebrex*, 2012 U.S. Dist. LEXIS 111446, at *220-23; *S. Ill. Laborers & Employers Health & Welfare Fund v. Pfizer Inc.*, 2009 U.S. Dist. LEXIS 91414, at *6, 19-20 (S.D.N.Y. Sept. 30, 2009); *Dist. 1199P Health & Welfare Plan v. Janssen, L.P.*, 784 F. Supp. 2d 508, 527 (D.N.J. 2011).

In these cases, courts have held that a TPP plaintiff cannot plead but-for causation through “generalized” or conclusory allegations that the named defendant’s alleged promotional efforts caused sales of prescription medications. *Janssen*, 784 F. Supp. 2d at 527. Rather, a TPP must plead concrete facts indicating that someone in the decisional chain (such as an insured’s physician or the TPP itself) was actually induced by the defendant’s alleged acts of racketeering to prescribe or pay for the defendant’s medication. *Id.* Thus, the courts have held that a TPP “need[s]” to allege facts describing (1) the “false, misleading or otherwise fraudulent” nature of information allegedly provided by a pharmaceutical defendant; (2) “the extent to which [a particular doctor or a payor] relied upon” that information when prescribing a drug or deciding to pay for the prescribed drug; and (3) that the drug would not have been prescribed or paid for absent the pharmaceutical defendant’s alleged conduct. *Actimmune*, 614 F. Supp. 2d at 1052; *accord Bextra & Celebrex*, 2012 U.S. Dist. LEXIS 111446, at *220-23 (in TPP’s RICO action, allegations of either first-party or third-party reliance on misrepresentations are necessary and “must be specific and factual in nature”); *S. Ill. Laborers*, 2009 U.S. Dist. LEXIS 91414, at *6,

19-20 (dismissing complaint where TPP “d[id] not cite a single instance in which [an insured’s] physician received the fraudulent information and decided to prescribe Lipitor based on the information she received”); *Janssen*, 784 F. Supp. 2d at 528 (“generalized allegations do not provide the requisite particularity” about how pharmaceutical company misled and induced doctors, patients, and TPPs) (internal quotations omitted).

Here, MMO’s Complaint makes only generalized allegations that the Defendant groups “caused” doctors to prescribe their respective TRT drugs for off-label uses and thereby “caused” MMO to pay for such prescriptions. (*E.g.*, Compl. ¶¶ 10, 23-29, 610-11.) The Complaint contains *no* concrete allegations establishing that any payment by MMO was the result of the challenged conduct of any Defendant and not the independent action of a different Defendant, doctor, patient, or other party not before the Court. Still less does the Complaint contain concrete allegations establishing that *each* Defendant was the but-for cause of injury to MMO. For example, there are no concrete allegations describing (1) the false, misleading or fraudulent nature of information allegedly provided by each Defendant; (2) “the extent to which” a particular doctor relied upon that information when prescribing that Defendant’s TRT drug; or (3) the extent to which MMO or another party relied on that information when deciding to include that Defendant’s TRT drug in MMO’s formulary and to pay for prescriptions of that Defendant’s TRT drug. Nor are there concrete allegations that each Defendant’s TRT drug would not have been prescribed, covered, and paid for absent the Defendant’s alleged acts of mail or wire fraud. *Actimmune*, 614 F. Supp. 2d at 1052. Because MMO’s Complaint fails to make such allegations against each Defendant, its RICO claims should be dismissed.

C. MMO Fails To Plead A Cognizable Injury

MMO also lacks standing to sue under RICO because it has not alleged facts demonstrating that it sustained the type of economic injury to its business or property that RICO

protects. MMO fails to identify any prescription for which it paid that was medically unnecessary or inappropriate or that resulted in harm to one of its beneficiaries.

The mere purchase of a prescription drug to treat an off-label condition is not a cognizable injury to a plaintiff's "business or property" within the meaning of 18 U.S.C. § 1964(c), even if the drug was purchased as a result of off-label promotion. The Supreme Court has made clear that there is nothing inherently injurious about the sale and use of prescription drugs to treat off-label conditions. To the contrary, off-label use of pharmaceuticals is "valu[able]," "prop[er]," and "often ... essential to ... optimal medical care." *Buckman v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 n.5 (2001). Courts have therefore been "[un]willing to accept that a plaintiff could somehow be injured" within the meaning of RICO "simply because the drug [it purchased] was marketed off-label." *In re Schering-Plough Corp. Intron/Temodar Consumer Class Action*, 2009 U.S. Dist. LEXIS 58900, at *33-40 (D.N.J. July 10, 2009), *aff'd*, 678 F.3d 235 (3d Cir. 2012). Rather, to allege a cognizable "injury to ... business or property," a plaintiff must allege facts that show it paid for a prescription drug that (1) was not medically necessary or appropriate for its beneficiary or (2) harmed the beneficiary. *Id.* at *38, *56 (plaintiff must allege it failed to receive the benefit of its bargain); *Maio v. Aetna*, 221 F.3d 472, 487-88 (3d Cir. 2000) (same); *Pirelli*, 631 F.3d at 443-45 (complaint dismissed because it contained no "firsthand facts or data" plaintiff was injured by defendants' scheme).

Similarly here, MMO fails to identify any instance in which it paid for a TRT drug that was medically unnecessary or inappropriate as to a particular beneficiary. *See Intron/Temodar*, 2009 U.S. Dist. LEXIS 58900, at *91-92. MMO also fails to plead concrete facts showing that even one of its beneficiaries was harmed by a TRT prescription. *See Janssen*, 784 F. Supp. 2d at 521-22 (no injury where plaintiffs "d[id] not identify any [beneficiary] who received an

ineffective or unsafe off-label ... prescription”). Still less does MMO plead such facts with respect to the TRT drugs manufactured by *each* of the Defendants sued in this case. Accordingly, MMO’s RICO claims should be dismissed.

D. In Analogous Circumstances, Courts Have Dismissed TPP Actions In Their Entirety For Lack Of Article III Standing

As noted above, there is an overwhelming body of law supporting the dismissal of MMO’s RICO claims for lack of statutory standing. In addition, for similar reasons, many courts have held that TPPs fail to establish Article III standing to support their RICO and state law claims when they fail to (1) identify specific prescriptions for which they paid, (2) allege facts demonstrating that those prescriptions were actually medically unnecessary, inappropriate, or harmful as to a particular beneficiary, and (3) allege that their alleged economic injuries were “fairly traceable to the challenged action ... and not the result of the independent action of some third party not before the Court.” *Lujan*, 504 U.S. at 560.

In those circumstances, courts have found that TPPs have not alleged a sufficiently concrete and particularized injury-in-fact. *See Travelers Indem. Co. v. Cephalon*, 32 F. Supp. 3d 538, 546-49 (E.D. Pa. 2014) (finding no standing where plaintiff did not allege facts “to show that they paid for an ineffective drug,” “that the drugs’ safety risks resulted in some expenditure by the plaintiffs,” or that “plaintiffs paid for a more expensive drug”); *Plumbers and Pipefitters Local 572 Health and Welfare Fund v. Merck & Co.*, 2013 WL 1819263, at *6-7 (D. N.J. Apr. 29, 2013) (lack of standing, in part, on the “failure to allege distinct instances in which Plaintiffs were forced to purchase medications they otherwise would not have, if not for the existence of the Programs”). In that regard, the chain-of-causation is far too attenuated and dependent on the independent actions of third-parties (physicians, among others) to support causation under Article III. *See Intron/Temodar*, 678 F.3d at 245-52 (no standing where TPP failed to “allege

facts sufficient to show that the [subject drug] which it paid for was prescribed to its members for ineffective off-label uses *because of* Schering's alleged misconduct"); *New England Carpenters Health and Welfare Fund v. GlaxoSmithKline, LLC*, 2014 WL 4119410, at *1 n.1 (E.D. Pa. Aug. 8, 2014) (same); *Plumbers and Pipefitters*, 2013 WL 1819263, at *6-7 (no standing where the complaint "is based on pure conjecture about the actions and motivations of unidentified doctors and unidentified patients with respect to unidentified prescriptions and unidentified payments by [Plaintiff]" (internal quotation marks omitted)); *Actimmune*, 2010 WL 3463491, at *11 ("Because all of the plaintiffs have failed to adequately plead causation, they lack standing to pursue any ... claims predicated on defendants' alleged violations...."); *S. Ill. Laborers*, 2009 WL 3151807, at *5-7, 8 (dismissing RICO and state law claims where plaintiffs did "not cite a single instance in which a physician received the fraudulent information and decided to prescribe [the subject drug] based on the information she received"). Given the similarities between the TPP complaints in these cases and MMO's Complaint, the Court should dismiss this entire action for lack of Article III standing under Rule 12(b)(1).

II. MMO Does Not Allege Any Predicate Act Of Mail Or Wire Fraud With The Particularity Required By Rule 9(b)

In addition to the Complaint's other failures, MMO's RICO claims must be dismissed because, while MMO alleges that each Defendant violated RICO by conducting the affairs of various promotional "enterprises" through a pattern of mail and wire fraud, MMO has not stated the circumstances of each individual Defendant's purported acts of mail or wire fraud with particularity. Without such allegations, MMO fails to adequately plead a violation of RICO.⁵

⁵ This Court's recent decision denying several motions to dismiss personal injury claims brought by TRT consumers is not to the contrary. *TRT*, 2014 WL 7365872, at *6-*8. The Court's decision concerned claims brought by plaintiff consumers who allegedly saw and relied on TRT advertisements and then sustained physical injuries allegedly as a direct result of taking TRT drugs. The claims here are very different: MMO's theory is that each Defendant deceived an

It is settled that, when a RICO violation is based on an alleged pattern of mail or wire fraud, the predicate acts must be supported by allegations stating the circumstances of the fraud with particularity. *McDonald v. Schencker*, 18 F.3d 491, 495 (7th Cir. 1994) (“Rule 9(b) ... requires RICO plaintiffs, like any other plaintiffs pleading fraud in the federal courts, to plead ‘all averments of fraud with particularity.’”) (citations omitted). Allegations consistent with Rule 12(b) and *Iqbal* are not enough. *See Vicom, Inc. v. Harbridge Merch. Servs., Inc.*, 20 F.3d 771, 777 (7th Cir. 1994).

Federal courts are particularly vigilant in scrutinizing pleading of RICO claims “because of the relative ease with which a plaintiff may mold a RICO pattern from allegations that, upon closer scrutiny, do not support it.” *Kolar v. Preferred Real Estate Invs., Inc.*, 361 F. App’x 354, 363 (3d Cir. 2010) (internal quotation marks and citation omitted). To satisfy Rule 9(b), a RICO plaintiff must “state with particularity” “the who, what, when, where, and how” of the alleged fraudulent acts. *Vicom*, 20 F.3d at 777 (internal quotations and citations omitted). Put differently, the complaint must state “the identity of the person who made the misrepresentation, the time, place and content of the misrepresentation, and the method by which the misrepresentation was communicated to” the party that relied upon it. *Id.* (internal quotations and citations omitted) (affirming the dismissal of a RICO claim predicated on multiple acts of mail and wire fraud because the complaint failed to satisfy Rule 9(b)).

Here, MMO makes only generic allegations of mail or wire fraud against each Defendant. (Compl. ¶¶ 80, 123, 132, 618-20.) The Complaint contains **no** concrete allegations about the time, place, and content of any alleged misrepresentation by (or attributable to) a Defendant that

intermediary doctor who wrote TRT prescriptions, as well as MMO itself; yet, the Complaint contains no well-pled factual averments identifying the “who, what, where, and when” of the alleged deception of any identifiable intermediary physician or of MMO.

caused MMO harm; the identity of the person who made the alleged misrepresentation; or the identity of the person who received the alleged misrepresentation and relied on it. *See Janssen*, 784 F. Supp. 2d at 527. The Complaint also does **not** explain what made a particular statement false, misleading, or fraudulent; nor does it provide any particular facts showing that a doctor subsequently wrote a prescription for each Defendant's TRT medication in reliance on the information he received from that Defendant or at that Defendant's behest. Likewise, MMO does **not** identify any fraudulent statement made by a Defendant to a representative of MMO or allege that MMO decided to pay for a TRT prescription without restriction in reliance on that Defendant's statement.⁶

MMO cannot state a RICO claim against any Defendant without alleging the predicate acts of mail and wire fraud of that Defendant with particularity. It has not satisfied this requirement, and thus, its RICO claims must be dismissed.⁷

III. MMO's RICO Claims Are Time-Barred

Statutes of limitations "protect important social interests in certainty, accuracy, and repose." *Cada v. Baxter Healthcare Corp.*, 920 F.2d 446, 453 (7th Cir. 1990). They are especially vital in RICO cases, because the "purpose" of RICO's heightened damage awards is "encouraging potential private plaintiffs **diligently to investigate.**" *Klehr v. A.O. Smith Corp.*,

⁶ Although the Complaint describes some details about CME courses, presentations, printed materials, and television and print advertisements (*see, e.g.*, ¶¶ 406, 424-28), it does not explain what made a particular statement false or misleading or identify who received and relied upon such information. Absent such facts, MMO cannot state a claim that complies with Rule 9(b). *See Midw. Grinding Co. v. Spitz*, 976 F.2d 1016, 1020 (7th Cir. 1992).

⁷ Because MMO lacks standing to sue under RICO and Article III and has not alleged a substantive RICO violation, MMO's claim against each Defendant group based on alleged conspiracies that that group had with unnamed third parties to commit a civil RICO violation must be dismissed as well. *Stachon v. United Consumers Club, Inc.*, 229 F.3d 673, 677 (7th Cir. 2000); *Walgreen*, 719 F.3d at 856-57. As noted above, the Complaint does not allege any conspiracy or collaboration across the various Defendant groups.

521 U.S. 179, 187 (1997) (emphasis added); *see also Jay E. Hayden Found. v. First Neighbor Bank, N.A.*, 610 F.3d 387-88 (7th Cir. 2010) (strictly construing RICO's time-bar).

A complaint should be dismissed as time-barred at the pleadings stage where, as here, “the issue c[an] be resolved ... based on the allegations in the complaint” and “facts within [the court’s] judicial-notice power.” *Ennenga v. Starns*, 677 F.3d 766, 773 (7th Cir. 2012). “Where the facts needed for determination of when a reasonable [plaintiff] ... would have been aware of [something] can be gleaned from the complaint and papers integral to the complaint, resolution of the issue on a motion to dismiss is appropriate, and [courts] have done so in a vast number of cases.” *LC Capital Partners, L.P. v. Frontier Ins. Grp.*, 318 F.3d 148, 156 (2d Cir. 2003) (ellipses, quotation marks, and citations omitted).

Civil RICO's statute of limitations is four years, and it “beg[ins] to run once ... the plaintiffs knew *or should have known* that they were injured.” *McCool v. Strata Oil Co.*, 972 F.2d 1452, 1464-65 (7th Cir. 1992) (emphasis added). In other words, even if the plaintiff did not actually know of his injury, the statute nevertheless begins to run when he “[w]ould have learned [of his injury] through the exercise of ordinary diligence in the protection of [his] legal rights.” *Fujisawa Pharm. Co. v. Kapoor*, 115 F.3d 1332, 1334 (7th Cir. 1997).

“[T]he focus is on the discovery of the harm itself.” *Cancer Found. v. Cerberus Capital Mgmt.*, 559 F.3d 671, 674-75 (7th Cir. 2009). Once the plaintiff knows (or should know) that “something amounting to injury in fact” has occurred, “it [is] up to him to inquire further,” learn the details, and sue within four years. *Perry v. Globe Auto Recycling, Inc.*, 227 F.3d 950, 954 (7th Cir. 2000). He need not know “*who* injured him” for the clock to start running; once he learns of an injury, “[h]e has the limitations period to discover that.” *Fidelity Nat’l Title Ins. Co. v. Howard Sav. Bank*, 436 F.3d 836, 839 (7th Cir. 2006) (emphasis added); *Robert L. Kroenlein*

Trust v. Kirchhefer, 764 F.3d 1268, 1279-80 (10th Cir. 2014). He need not know that his injury is “actionable,” *Cancer Found.*, 559 F.3d at 674-75, or even “that he has been wronged” in a lay sense, *Wolin v. Smith Barney Inc.*, 83 F.3d 847, 852 (7th Cir. 1996). Nor does he need to know about the underlying pattern of racketeering. *Rotella v. Wood*, 528 U.S. 549, 555 (2000).

A. MMO Has Failed To Allege Timely RICO Claims Against The AbbVie Defendants, Auxilium, And The Actavis Defendants

The Complaint alleges that the AbbVie Defendants, Auxilium, and Actavis Defendants began causing improper off-label prescriptions for TRT drugs to be submitted to MMO at least twelve years ago. (*See* Compl. ¶ 53 (AbbVie Defendants in 2000); ¶ 54 (Auxilium in 2002); ¶ 57 (Actavis Defendants in 1995).) The claims against these Defendants are time-barred, as long as MMO knew (or a reasonably diligent TPP in its position would have known) by November 5, 2010—*i.e.*, four years before MMO filed this suit—that “something amounting to injury in fact” had occurred. Accepting MMO’s allegations as true for purposes of this motion, there is no question that MMO should have known of its alleged injury in the exercise of reasonable diligence long before November 2010.

The recent decision in *United States ex rel. King v. Solvay S.A.*, 2015 U.S. Dist. LEXIS 25132 (S.D. Tex. Mar. 3, 2015), compels that answer. In 2003, *King* was filed by two former employees of Solvay Pharmaceuticals, Inc. (now known as AbbVie Products, LLC). *Id.* at *5-6. Those employees challenged the lawfulness of “Solvay’s” marketing of AndroGel (and two other drugs not at issue here). Just like MMO’s complaint, the *King* complaint (*see* Declaration of William F. Cavanaugh, Jr. (“Cavanaugh Decl.”), Ex. 1) alleged that “Solvay” had commissioned medical articles on off-label uses and influenced physician speakers to promote those uses. *See also United States ex rel. King v. Solvay S.A.*, 823 F. Supp. 2d 472, 482 (S.D. Tex. 2011) (describing *King* allegations).

Recently, the *King* court dismissed the portion of the complaint relating to AndroGel because the alleged off-label promotion was a matter of public record before those purported “whistleblowers” filed suit in 2003:

[A July 2002 feature] *New Yorker* article, entitled “Hormones for Men: Is Male Menopause a Question of Medicine or of Marketing?,” discusses advertisements for male menopause that were [allegedly] paid for by Unimed, “a division of ... Solvay.” It notes that Unimed makes AndroGel. [It] discusses the possibility of the pharmaceutical industry “inventing” diseases, such as andropause or male menopause. It highlights a doctor that ... urged men who were experiencing a low sex drive or low energy to have their testosterone levels checked at his clinic. The advertisement and the tests were allegedly underwritten by ... Unimed

The article points out that a physician may prescribe a drug for any clinical condition once it is approved by the FDA, but that the “FDA prohibits drug companies from advertising ‘off label’ uses,” and “andropause” was not an approved use. It also discusses an andropause conference convened by the Endocrine Society that [allegedly] was solely financed by a Unimed/Solvay grant. Nine out of the thirteen panelists in the final group [allegedly] had “significant financial ties to Unimed/Solvay.” The panel ultimately recommended that patients over fifty should be screened with [the ADAM] questionnaire about andropause These recommendations [allegedly] [did] not [disclose] the financial ties that the majority of the panelists had to Unimed/Solvay. The article ... also points out that there is “a lot of uncertainty about the effects of age-related lowering of testosterone,” questions ... testosterone’s effectiveness for preventing bone fractures, and points to many “worrisome” [alleged] side effects of testosterone treatment.

King, 2015 U.S. Dist. LEXIS 25132, at *21-22 (citations omitted). The *King* court concluded that this 2002 *New Yorker* article, standing on its own, was “enough to put [a plaintiff] on the trail of the [alleged] fraud.” *Id.* at *22. (See Cavanaugh Decl., Ex. 26 (*New Yorker* article).)

As a sophisticated entity, a TPP such as MMO “is presumed to have information available in the public domain,” especially feature stories published in prominent national magazines. *Whirlpool Fin. Corp. v. GN Holdings*, 67 F.3d 605, 610 (7th Cir. 1995).⁸ MMO,

⁸ Because the existence of these news sources is a matter of public record, the Court may take judicial notice of them. *Specht v. Google, Inc.*, 758 F. Supp. 2d 570, 586 (N.D. Ill. 2010), *aff’d*, 747 F.3d 929 (7th Cir. 2014); *see also Ennenga*, 677 F.3d at 773 (on a motion to dismiss, courts

therefore, was on notice that it had suffered “something amounting to an injury in fact” no later than July 2002—well over *twelve years* before it filed this suit.

Submitted herewith as exhibits to the Cavanaugh Declaration are dozens of additional news stories (including a number of front-page articles) from major news organizations concerning TRT drugs published between February 2000 and June 2010. They address allegations of: off-label use for “andropause”; off-label use in women; whether “andropause” is a genuine medical condition; side effects, including heart attacks; “off-label” advertisements, websites, questionnaires, and other consumer-directed materials (including the ADAM questionnaire and other materials discussed in the Complaint); and “off-label” medical articles that certain Defendants allegedly financed.⁹

Moreover, on May 7, 2009, the FDA announced that it was requiring TRT gel products (AndroGel and Testim) to bear additional warnings. (Compl. ¶¶ 63, 589.) In its announcement, the FDA claimed that, in 2007, “[a]pproximately 25,000 [TRT prescriptions] were dispensed for off-label use in women.” See FDA Press Release (May 7, 2009), <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2009/ucm149580.htm>.¹⁰ At that time, numerous news outlets reported on this press release and repeated its claim about “off-label use in women.” (See, e.g., Cavanaugh Decl., Exs. 47-48.) These allegations, which form part of MMO’s alleged

may consider “facts within [their] judicial-notice power”). Defendants do not offer the contents of these articles for their truth, which Defendants affirmatively dispute. Defendants ask the Court to take notice that the allegations they contained *were in the public record* as of the time of publication.

⁹ Indeed, one of those articles is cited in MMO’s Complaint. (Compl. ¶ 6 (citing Gina Kolata, *Male Hormone Therapy Popular But Untested*, New York Times (Aug. 19, 2002) (Cavanaugh Decl., Ex. 28).) The Court may take judicial notice of this article since the Complaint itself relies on it. See *United States v. Wood*, 925 F.2d 1580, 1582 (7th Cir. 1991).

¹⁰ The Court may take judicial notice of press release both because it is a published government document, see *Bova v. U.S. Bank, N.A.*, 446 F. Supp. 2d 926, 931 n.2 (S.D. Ill. 2006), and because the Complaint refers to the FDA warning at issue, see *Wood*, 925 F.2d at 1582.

injury here (*see* Compl. ¶¶ 148, 150, 182, 214-19), were therefore public at least a year and a half before the November 2010 cutoff date.

Further, MMO's own Complaint alleges that, "in June 2010"—at least four months before the November 5, 2010 cutoff date—the prominent New England Journal of Medicine published a study revealing a “dramatic[]” connection between TRT use and “adverse cardiovascular effects.” (Compl. ¶ 580; *see* Cavanaugh Decl., Ex. 55) This study's results were immediately announced by the National Institutes of Health and reported across the country. (*See* Cavanaugh Decl., Exs. 56-67, 69-70, 73.)

Finally, the *King* complaint (Cavanaugh Decl., Ex. 1), which addressed in detail the same off-label “enterprises” alleged in MMO's complaint, was a matter of public record by December 7, 2009—nearly a year before the November 5, 2010 cutoff date. *See* Mem. and Order, No. 4:06-cv-02662, Dkt. 110 at 1 (S.D. Tex. July 20, 2010) (noting date of unsealing); *King*, 2015 U.S. Dist. LEXIS 25132, at *6 (same).¹¹

These public sources establish—as a matter of law—that any reasonably diligent entity in MMO's position would have learned of its alleged injury, years before November 2010. Accordingly, this lawsuit was hopelessly time-barred when MMO filed it in November 2014.

In assessing the level of diligence that MMO should have exercised, this Court should bear in mind that MMO is not an individual consumer, but one of the nation's “oldest and largest health insurance compan[ies],” purporting to represent a class of large and sophisticated entities.

¹¹ *See* *Pirelli*, 631 F.3d at 443 (“tak[ing] judicial notice of the complaint in [a related] *qui tam* case”). MMO alleges that it “was not aware of the [*King*] case” until recently (Compl. ¶ 604), but accrual turns on what a diligent entity in MMO's position would have known, not what MMO *in fact* knew. MMO also alleges that “virtually all of the [*King*] complaint's *exhibits* relating to AndroGel remain under seal” (*id.* (emphasis added)), but even if that were true, the *King* complaint itself, even without exhibits, contains more than enough detail to put a reasonable TPP on notice of a potential claim.

(*About Medical Mutual*, <https://www.medmutual.com/About-Medical-Mutual.aspx> (visited March 1, 2015); *see also* Compl. ¶ 30.) TPPs such as MMO are “sophisticated institutions” with considerable “expertise in merchandising of [p]harmaceuticals.” *In re Zyprexa Prods. Liab. Litig.*, 253 F.R.D. 69, 195-96 (E.D.N.Y. 2008), *rev’d on other grounds*, 620 F.3d 121 (2d Cir. 2010); *Sidney Hillman Health Ctr. of Rochester v. Abbott Labs.*, 2014 U.S. Dist. LEXIS 112634, at *12 (N.D. Ill. Aug. 14, 2014). The “have the best information” “[of] all entities in society” about healthcare matters. *Philip Morris*, 196 F.3d at 826. When the plaintiff is an “experienced corporate player,” a “different quantum of expertise and knowledge is in play,” and a “forgiving application of the discovery rule” is not “justified.” *KDC Foods v. Gray*, 763 F.3d 743, 751 (7th Cir. 2014) (for sophisticated plaintiff, facts sufficient to create “initial suspicion” were enough “to trigger [constructive] discovery of [the] alleged injury”).

B. MMO Cannot Establish Any Tolling Of RICO’s Statute Of Limitations

MMO pleads that the statute of limitations “ha[s] been tolled by Defendants’ fraudulent concealment.” (Compl. ¶ 596.) To that end, it alleges that Defendants’ “techniques of secrecy” “prevent[ed] [it] ... from discovering” its “potential claims until shortly prior to the filing of the Complaint,” and that MMO “could not have acquired ... knowledge” of a potential claim sooner “through the exercise of reasonable diligence.” (*Id.* ¶¶ 597, 600.) These conclusory allegations do not meet even the pleading standard of Rule 8, let alone the heightened standard of Rule 9(b), which applies to allegations of fraudulent concealment. *See Dummar v. Lummis*, 543 F.3d 614, 621 (10th Cir. 2008); *Wolin*, 83 F.3d at 854.

The Supreme Court has held that “a plaintiff who is not reasonably diligent may not assert ‘fraudulent concealment’” to escape RICO’s statute of limitations. *Klehr*, 521 U.S. at 194-95. It is not enough that diligent investigation would allegedly have been futile; a plaintiff must *actually have made* a diligent effort. *Id.* MMO does not allege that it *actually employed* any

diligence to investigate the widespread public reports about TRT drugs set forth above. This is fatal. *See Hentosh v. Herman M. Finch Univ.*, 167 F.3d 1170, 1175 (7th Cir. 1999); *Davenport v. A.C. Davenport & Son Co.*, 903 F.2d 1139, 1142 (7th Cir. 1990); *Dummar*, 543 F.3d at 621.

Moreover, MMO cannot plausibly establish the requisite “causal” connection between Defendants’ alleged acts of concealment and its failure to sue timely. *Jay E. Hayden Found.*, 610 F.3d at 385; *see also Flight Attendants Against UAL Offset v. Comm’r*, 165 F.3d 572, 577 (7th Cir. 1999) (“[T]he conduct alleged ... [must] have been the cause of the plaintiff’s not suing in time.”). There was more than enough information in the public record, many years before the critical November 2010 date, for a “reasonable” TPP to perceive at least “the *possibility* that [its] rights ha[d] been violated”—and that is enough to preclude tolling. *Chapple v. Nat’l Starch & Chem. Co.*, 178 F.3d 501, 506 (7th Cir. 1999) (emphasis added); *see also Whirlpool*, 67 F.3d at 610 (“[Because] the information Whirlpool needed to uncover the fraud was in the public domain, GN’s continued attempts to [obfuscate] ... could not have prevented Whirlpool from filing its complaint on time.”); *Dummar*, 543 F.3d at 622 (same).

C. MMO’s RICO Claims Against Lilly And Endo Fail As Well

The RICO claims against Lilly and Endo are not time-barred, because those Defendant groups entered the TRT market within the past four years. (*See* Compl. ¶ 56 (Lilly Defendants the first quarter of 2011); ¶ 58 (Endo in December 2010).) However, the public information discussed above scuttles MMO’s claims against these recent market entrants on a different doctrinal ground.

By late 2010 and 2011, when the Lilly and Endo Defendants entered the market, any reasonably diligent doctor or TPP would have been aware of the allegations that TRT drugs were being promoted and prescribed for off-label uses and of allegations concerning TRT drugs’ benefits and risks. There was never a time, in other words, when the Lilly and Endo Defendants

could have *deceived* a reasonable doctor or TPP in the manner alleged. Thus, MMO could not plausibly plead that these Defendant groups committed the alleged predicate acts of mail fraud and wire fraud, or that those predicate acts (rather than MMO's own intervening negligence or willful inaction) proximately caused MMO's alleged losses. See *Reynolds v. E. Dyer Dev. Co.*, 882 F.2d 1249, 1253 (7th Cir. 1989) (plaintiff's RICO claim failed because the facts allegedly concealed were a matter of public record; a RICO plaintiff "may not rely on misrepresentations when he has sufficient information to call the misrepresentation into question"); *Drobny v. JP Morgan Chase Bank*, 929 F. Supp. 2d 839, 849 (N.D. Ill. 2013) (a statement "upon which no reasonable person could rely" cannot "amount to wire or mail fraud for purposes of RICO").¹²

IV. MMO's State Law Claims Must Be Dismissed

In addition to its RICO claims, MMO asserts state law claims against each Defendant. In particular, MMO asserts a claim against each Defendant for alleged violations of the consumer protection statute in the state where that Defendant allegedly is located.¹³ In separate counts, MMO also purports to assert claims against each Defendant under the laws of the consumer

¹² In *Bridge*, the Supreme Court stated that "first-party reliance" is not, on its own, "an indispensable requisite" of a RICO claim predicated on mail fraud. 553 U.S. at 658-59. At the same time, the Supreme Court noted that "the absence of first-party reliance" may "prevent the plaintiff from establishing [the required element of] proximate cause," because the voluntary assumption of an injury "break[s] the chain of causation between [a defendant's] misrepresentations and [the resulting] injury." *Id.* The cases cited in the text, therefore, remain good law.

¹³ Specifically, MMO asserts a claim against: (i) the AbbVie Defendants for alleged violations of the Illinois Consumer Fraud Act (Twenty First Claim for Relief); (ii) Auxilium for alleged violations of Pennsylvania's Unfair Trade Practices and Consumer Protection Law (Twenty Fourth Claim for Relief); (iii) Lilly for alleged violations of Indiana's Deceptive Consumer Sales Act (Twenty Seventh Claim for Relief); (iv) the Actavis Defendants for alleged violations of New Jersey's Consumer Fraud Act (Twenty Ninth Claim for Relief); and (v) Endo for alleged violations of Pennsylvania's Unfair Trade Practices and Consumer Protection Law (Thirty Second Claim for Relief).

protection statutes of every other state, the District of Columbia, and Puerto Rico.¹⁴ In addition, MMO asserts claims against the AbbVie Defendants, Auxilium, the Actavis Defendants, and Endo for alleged violations of insurance fraud statutes in the states where those Defendants allegedly are located.¹⁵ MMO further asserts claims against each Defendant for common law fraud (Thirty-Fifth Claim for Relief), negligent misrepresentation (Thirty-Sixth Claim for Relief), unjust enrichment (Thirty-Seventh Claim for Relief), and equitable, injunctive relief (Thirty-Eighth Claim for Relief). All of these claims should be dismissed.

A. MMO's Consumer Protection And Insurance Fraud Claims Should Be Dismissed

1. The Consumer Protection And Insurance Fraud Statutes Of The States In Which Each Defendant Is Located Do Not Apply Under Governing Choice Of Law Principles

“In an MDL proceeding, ‘a transferee court applies the substantive state law, including choice-of-law rules, of the jurisdiction in which the action was filed.’” *TRT*, 2014 WL 7365872, at *10 (citation omitted). This action was filed under Case Management Order No. 12 (“CMO 12”) (Dkt. No. 440), which provides that any directly-filed case will be treated “as if it was originally filed in the federal district where the Plaintiff [is] a citizen” and that direct filing “will have no impact on choice of law.” *Id.* at II.B.i and II.F.

¹⁴ See Twenty Second Claim for Relief (AbbVie Defendants); Twenty Fifth Claim for Relief (Auxilium); Twenty Eighth Claim for Relief (Eli Lilly); Thirtieth Claim for Relief (Actavis Defendants); Thirty Third Claim for Relief (Endo). Although MMO purports to assert claims under the consumer protection statute of every state against each Defendant, it does not allege violations of the consumer protection statutes of Alabama, Georgia, Maine, Massachusetts, Mississippi, Texas, and West Virginia against any Defendant.

¹⁵ Specifically, MMO asserts a claim against (i) the AbbVie Defendants for alleged violation of Illinois’ Insurance Fraud statute (Twenty Third Claim for Relief); (ii) Auxilium for alleged violation of Pennsylvania’s Insurance Fraud statute (Twenty Sixth Claim for Relief); (iii) the Actavis Defendants for alleged violation of New Jersey’s Insurance Fraud statute (Thirty First Claim for Relief); and (iv) Endo for alleged violation of Pennsylvania’s Insurance Fraud statute (Thirty Fourth Claim for Relief).

MMO alleges that it is an Ohio citizen. (Compl. ¶ 30.) Under CMO 12, this case should be treated as if it were filed in a federal district court in Ohio. A federal district court in Ohio would apply Ohio's choice-of-law rules to determine the law that applies to MMO's state law claims. *See Muncie Power Prods., Inc. v. United Techs. Automotive, Inc.*, 328 F.3d 870, 873 (6th Cir. 2003).

Under Ohio law, the principles in the Restatement (Second) of Conflict of Laws govern choice-of-law determinations in tort cases. *See Morgan v. Biro Mfg. Co., Inc.*, 474 N.E.2d 286, 288-89 (Ohio 1984).¹⁶ “[U]nder the Second Restatement, the Court must apply a ‘two-step process in which the court (1) chooses a presumptively applicable law under the appropriate jurisdiction-selecting rule, and (2) tests this choice against the principles of § 6 in light of relevant contacts identified by general provisions like § 145 (torts).’” *TRT*, 2014 WL 7365872, at *10 (citations and internal quotation marks omitted). Applying that analysis to MMO's tort claims, “‘the law of the place of injury controls unless another jurisdiction has a more significant relationship to the lawsuit.’” *Pilgrim v. Universal Health Card, LLC*, 660 F.3d 943, 946 (6th Cir. 2011) (quoting *Morgan*, 474 N.E.2d at 289); *accord TRT*, 2014 WL 7365872, at *11.

This Court concluded that the law of the state where each plaintiff was located applied to that plaintiff's state law tort claims seeking recovery for alleged personal injury. *Id.* The same result follows for MMO's state law tort claims seeking recovery for alleged economic injury. As the Seventh Circuit has held, “if recovery for ... consumer fraud is possible, the injury is decidedly where the *consumer* is located, rather than where the seller maintains its headquarters.” *In re Bridgestone/Firestone, Inc.*, 288 F.3d 1012, 1017 (7th Cir. 2002) (emphasis by Court). Similarly, the Sixth Circuit held in *Pilgrim*, considering the factors listed in sections

¹⁶ Illinois also “has adopted the approach of the Second Restatement of Conflict of Laws.” *TRT*, 2014 WL 7365872, at *10. Thus, the analysis would not differ under Illinois' rules.

6 and 145 of the Restatement (Second), that “the State with the strongest interest in regulating [alleged deceptive] conduct is the State where the consumers—the residents protected by *its consumer*-protection laws—are harmed by it.” 660 F.3d at 946 (emphasis by Court).¹⁷

As a result, under Ohio choice-of-law principles, “the place of the injury controls in a consumer-protection lawsuit, requiring application of the home-state law of each potential class member.” *Id.* at 947. Put simply, Ohio law, rather than the laws of the states in which each Defendant is allegedly located, applies to MMO’s state law claims. Accordingly, MMO’s claims under the consumer protection and insurance fraud statutes of the states in which each Defendant is allegedly located should be dismissed.¹⁸

2. MMO’s OCSPA Claims Should Be Dismissed Because MMO Has Not Engaged In A Consumer Transaction With Any Defendant

MMO’s claims under the Ohio Consumer Sales Practices Act (“OCSPA”)—the only statutory claims MMO could possibly assert—must be dismissed because MMO’s allegations are outside the scope of the statute’s plain terms. The OCSPA provides a remedy against “suppliers” for “unfair or deceptive act[s] or practice[s] in connection with a consumer transaction.” Ohio Rev. Code § 1345.02(A). A “consumer transaction” is defined as “a sale, lease, assignment, award by chance, or other transfer of an item of goods, a service, franchise, or an intangible, to

¹⁷ See also *Spence v. Glock*, 227 F.3d 308, 315 (5th Cir. 2000) (under the Restatement (Second) choice-of-law principles, the significance of the relationship of any state other than the place of injury is considered only when “the place of injury is fortuitous or bears little relation to the occurrence and the particular issue,” which “cannot be said to be true” in a case involving purely an “economic loss”).

¹⁸ MMO’s “‘catch-all’ listing” of various state consumer protection and other statutes “does not meet the most basic pleading requirements.” *Janssen*, 784 F. Supp. 2d at 531. And, MMO lacks standing to assert claims under state statutes and common law other than Ohio law. See *Actimmune*, 2009 WL 3740648, at *17 (dismissing state statutory claims for all states lacking a representative plaintiff that could assert claims thereunder). For these additional reasons, the Court should dismiss MMO’s consumer protection, insurance fraud and common law claims for all states other than Ohio.

an individual for purposes that are *primarily personal, family, or household*, or solicitation to apply any of these things.” Ohio Rev. Code § 1345.01(A) (emphasis added). A “consumer,” in turn, is defined as “a person who engages in a consumer transaction with a supplier.” Ohio Rev. Code § 1345.01(D).

The OCSA does not apply by its own plain text where, as here, the plaintiff is not “an individual.” See *Watkins & Son Pet Supplies v. Iams Co.*, 107 F. Supp. 2d 883, 893-94 (S.D. Ohio 1999) (“individual” in OCSA “mean[s] a natural person,” not a business entity); *Reeves v. PharmaJet, Inc.*, 846 F. Supp. 2d 791, 798 (N.D. Ohio 2012); *Williams v. Boston Scientific Corp.*, 2013 WL 1284185, at *6 (N.D. Ohio Mar. 27, 2013). Nor does it apply to a plaintiff, such as MMO, who made the disputed purchase “for purposes that are [not] primarily personal, family, or household.” *Reeves*, 846 F. Supp. 2d at 798 n.2; *Williams*, 2013 WL 1284185, at *6.¹⁹ Nor does the OCSA apply where, as here, the plaintiff did not engage in any transaction with the supplier. *Reeves*, 846 F. Supp. 2d at 798 n.2 (no claim where plaintiff’s transaction was with pharmacy not manufacturer); *Williams*, 2013 WL 1284185, at *6 (same where a hospital and not the plaintiff purchased medical device from the manufacturer).

3. MMO’s OCSA Claims Should Be Dismissed Because MMO Has Not Pleaded Facts That Would Permit It To Represent A Purported Class

MMO purports to assert its OCSA claims on behalf of a putative class of TPPs. MMO’s claims should be dismissed because the OCSA does not permit class claims under the circumstances pleaded.

¹⁹ See also *UFCW Local 1776 v. Teikoku Pharma USA, Inc.*, 2014 U.S. Dist. LEXIS 161069, at *93-94 (N.D. Cal. Nov. 17, 2014) (dismissing similar consumer-protection claim brought by TPP where TPP “d[id] not link [its] purchase to *its own* personal, family or household use” (emphasis added)); *Actimmune*, 2010 U.S. Dist. LEXIS 90480, at *37-38 (same); *In re K-Dur Antitrust Litig.*, 2008 U.S. Dist. LEXIS 113310, at n.23 (D.N.J. Mar. 19, 2008) (“[I]t is doubtful that a TPP’s claims ... could be construed to involve purchases made ... [for] personal, family or household purposes.”).

Under the OCSPA, claims may not be brought “in a class action,” unless the asserted violation was either (1) “an act or practice declared to be deceptive or unconscionable by [Ohio administrative regulation] before the consumer transaction on which the action is based,” or (2) “an act or practice determined by a court of [the] state [of Ohio] to violate [the OCSPA] and committed after the decision containing the determination has been made available for public inspection” Ohio Rev. Code § 1345.09(B). In other words, “a consumer ‘may qualify for a class action only when a supplier acted in the face of prior notice that its conduct was deceptive or unconscionable.’” *McKinney v. Bayer Corp.*, 744 F. Supp. 2d 733, 743 (N.D. Ohio 2010) (citation omitted). “A general rule is not sufficient to put a reasonable person on notice of the prohibition against a specific act or practice.” *Volbers-Klarich v. Middletown Mgmt., Inc.*, 929 N.E.2d 434, 441 (Ohio 2010). Rather, a plaintiff seeking to represent a class must affirmatively plead that Ohio regulations or state court decisions put the defendant on notice that its specific acts and conduct were deceptive or unconscionable. *See Marrone v. Philip Morris USA, Inc.*, 850 N.E.2d 31, 35 (Ohio 2006) (“prior determination [must] be specific and ... involve conduct similar to the alleged conduct at issue”). That requirement is a substantive rule of Ohio law that applies in diversity actions pending in federal court. *See Phillips v. Philip Morris Cos. Inc.*, 290 F.R.D. 476, 480 (N.D. Ohio 2013) (“every court ... has concluded that the [O]CSPA’s notice requirement is not displaced by Fed. R. Civ. P. 23” (citations omitted)).

MMO has not satisfied its burden to plead that any, much less each, Defendant’s specific conduct was deceptive or unconscionable under any preexisting Ohio regulation or previously decided Ohio state court decision. Accordingly, MMO’s “claim seeking certification of a class action alleging violation of the OCSPA fails to state a claim upon which relief can be granted.” *Volbers-Klarich*, 929 N.E.2d at 441; *accord Phillips*, 290 F.R.D. at 482 (granting defendants’

motion for judgment on the pleadings dismissing class claim under OCSPA); *McKinney*, 744 F. Supp. 2d at 749 (same).²⁰

B. MMO's State Law Claims Are Time-Barred

MMO's state law claims are barred under the governing statutes of limitations. Under Ohio law, MMO's common law fraud claims are governed by a four-year statute of limitations running from the date when "the plaintiff discovers or should have discovered the fraud." *Foster v. Wells Fargo Fin. Ohio, Inc.*, 960 N.E.2d 1022, 1025 (Ohio App. 8th Dist. 2011); Ohio Rev. Code § 2305.09(C).²¹ MMO's negligent misrepresentation claims are governed by a four-year statute of limitations running from the date of the alleged misrepresentation. *See Lasmer Indus., Inc. v. Am General, LLC*, 741 F. Supp. 2d 836-37 (S.D. Ohio 2010); Ohio Rev. Code § 2305.09(D). MMO's claims under the OCSPA are governed by a two-year statute of limitations running from the date of the alleged violation. *See Foster v. Wells Fargo Fin. Ohio, Inc.*, 960 N.E.2d 1022, 1024 (Ohio App. 8th Dist. 2011); Ohio Rev. Code § 1345.10(C). And MMO's unjust enrichment claims are governed by a six-year statute of limitations. *See Shury v. Greenaway*, 2014 WL 1513992, at *3 (Ohio App. 8th Dist. Apr. 17, 2014); Ohio Rev. Code § 2305.07. "The statute of limitations for an unjust enrichment claim is not subject to equitable tolling or a discovery rule." *Patel v. Krisjal, L.L.C.*, 2013 WL 1287344, at *7 (Ohio App. 10th

²⁰ Some of the other state consumer protection statutes under which MMO purports to assert claims also do not permit class actions for monetary damages. *See, e.g.*, La. Rev. Stat. Ann. § 51:1409(A); Mont. Code Ann. § 30-14-133; S.C. Code Ann. § 39-5-140(a). In addition, others require that a plaintiff provide, and plead, notice of the alleged violation to the defendant prior to commencing a lawsuit. *See, e.g.*, Ind. Code Ann. § 24-5-0.5-5(a).

²¹ "No more than a reasonable opportunity to discover the misrepresentation is required to start the period of limitations," and "[i]nformation sufficient to alert a reasonable person to the possibility of wrongdoing gives rise to a party's duty to inquire into the matter with due diligence." *Clemente v. Gardner*, 2004 WL 953700, at *3 (Ohio App. 5th Dist. Apr. 26, 2004).

Dist. Mar. 28, 2013).²² MMO incurred its claimed loss as early as 2000, and had reason to suspect potential wrongdoing by 2002 or earlier—long before this action. (*See supra* pp. 26-30.)

C. MMO’s State Law Claims Should Be Dismissed For Failure To Plausibly Allege Proximate Cause Or Justifiable Reliance

Proximate cause is an essential element of each of MMO’s state law claims.²³ The principles that apply to MMO’s RICO claims apply to its state law claims. *City of Cleveland v. Ameriquist Mortgage Secs., Inc.*, 621 F. Supp. 2d 513, 533 (N.D. Ohio 2009) (“Holmes controls the proximate cause analysis” under Ohio law); *Cleveland v. JP Morgan Chase Bank, N.A.*, 2013 WL 1183332, at *4 (Ohio App. 8th Dist. Mar. 21, 2013) (no claim exists “[w]here the injury is too remote or tenuous”). MMO has failed to allege proximate cause. (*See supra* pp. 8-17).

Under Ohio law, justifiable reliance is also an essential element of MMO’s claims for common law fraud, negligent misrepresentation, and under the OCSPA.²⁴ Specifically, “reliance on the part of the *plaintiff* is required.” *Lasmer Indus., Inc. v. AM Gen., LLC*, 741 F. Supp. 2d 829, 840 (S.D. Ohio 2010) (emphasis added). MMO has not alleged that it relied on any specific representation of any Defendant; nor does MMO allege that its Pharmacy Benefits Manager (“PBM”), any doctor who prescribed a TRT drug to an MMO beneficiary, or any MMO

²² MMO’s unjust enrichment claim should also be dismissed because it is duplicative of its fraud-based legal claims. (Compl. ¶¶ 1054, 1057, 1060.) *Love v. City of Port Clinton*, 524 N.E.2d 166, 167 (Ohio 1988) (citation omitted). Ohio law does not “allow[] a plaintiff to take advantage of a longer statute of limitations through creative pleading.” *Perez Bar & Grill v. Schneider*, 2010 WL 1227706, at *4 (Ohio App. 9th Dist. Mar. 31, 2010).

²³ *See Graham v. American Cyanamid Co.*, 350 F.3d 496, 507 (6th Cir. 2003) (common law fraud); *Phillips v. Philip Morris Cos., Inc.*, 298 F.R.D. 355, 366 n.15 (N.D. Ohio 2014) (unjust enrichment)(citing *Johnson v. Lindquist*, 2012 WL 5945965, at *2 (Ohio App. 10th Dist. Nov. 27, 2012)); *Butler v. Sterling, Inc.*, 210 F.3d 371, 2000 WL 353502, at *4 (6th Cir. 2000) (OCSPA claim); *Westfield Ins. Co. v. HULS Am., Inc.*, 714 N.E.2d 934, 951 (Ohio App. 10th Dist. 1998) (negligent misrepresentation).

²⁴ *See Mishler v. Hale*, --- N.E.3d ---, 2014 WL 746310, at *8 (Ohio App. 2d Dist. Dec. 31, 2014) (fraud); *Heinz & Assoc., Inc. v. Diamond Cellar Holdings, L.L.C.*, 2012 WL 1079087, at *4-*10 (Ohio App. 10th Dist. Mar. 30, 2012) (negligent misrepresentation).

beneficiary did so. MMO's general allegations (Compl. ¶¶ 1039, 1048) amount to "a formulaic recitation of the elements of a cause of action," and "naked assertion[s]," which are insufficient to satisfy Rule 8(a), *Iqbal*, 556 U.S. at 678, let alone Rule 9(b).

CONCLUSION

For each of these reasons, the Court should dismiss MMO's Complaint with prejudice.

Dated: March 16, 2015

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on March 16, 2015, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system which sent notification of such filing to all registered attorneys of record.

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